Journal of
APPLIED PACKAGING RESEARCH
RESEARCH ARTICLE

Unpackaging Aseptic Presentation: A Qualitative Study into the Contextual Influences Involving Medical Packaging Design and Use Heuristics Among Perioperative Personnel

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ABSTRACT

Newly emerging mandates in the Medical Device Regulation in Europe and additions to ISO 11607 require medical device manufacturers characterize how package designs facilitate (or hinder) aseptic transfer by perioperative personnel. The present work utilized a semi-structured interview with clinicians on the topic of aseptic presentation. Methodological decisions related to the interviews and assessment of results were undergirded with affordance and situated learning theories to identify the components of a user experience. QDA Miner software was used post-hoc to code, quantify, and categorize the data into major and minor themes. The study identifies several components within the user's experience that influenced aseptic transfer, including: context (e.g. staff availability), coworkers' input, and variation in individuals' interpretation of acceptable practice related to the transfer of devices to the sterile field and appropriate handling of packaging. To comply with the changing regulatory landscape surrounding the safety of medical devices, the industry should employ human factors methodologies to better understand how sterile packages will be used by the clinician "aseptically".

KEY WORDS

Human factors, Sterile Packaging, Usability, Aseptic Technique

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BACKGROUND

Usability of medical packaging has always been a consideration for those creating sterile barrier systems (SBS) in accordance with ANSI/AAMI/ISO 11607, part 1. Specifically, the standard calls for packaging to "allow sterilization, provide physical protection, maintain sterility to the point of use, and allow aseptic presentation [emphasis added]" [1]. Aseptic presentation is defined by the standard as the "transfer of contents from its sterile barrier system [SBS] using conditions and procedures that minimize the risk of microbial contamination" [1]. Though this language has long existed in the standard, there has not been a wide-spread, concerted effort to measure performance related to a design's ability to enhance, or hinder, aseptic transfer. While a limited number of companies have opportunities to observe point-of-use, more interpret what usability means to design verification and design validation activities through conjecture. Non-simulated use, such as marketing voice-of-customer panels, are often as much as the engineer can expect. The engineer is left with a very limited window into the customer's actual needs and requirements.

Recent developments in both regulations and international standards have placed enhanced emphasis on the objective characterization of how a given package design influences aseptic transfer. New requirements released by the European Parliament and the Council of the European Union as part of the new Medical Device Regulation (MDR) and the InVitro Diagnostic Regulation (IVDR) add sections which require packaging that (b) "[facilitates] easy and safe handling" and (d) "prevent[s] microbial contamination of the device or its content such as specimens or fluids" [2]. In parallel to the European regulations, recent changes to ISO 11607 require the manufacturers of medical devices to provide a documented usability evaluation to demonstrate that the sterilized device can be aseptically removed from the packaging. Under this frame, usability studies intend to demonstrate that the user can identify the opening feature, perform the technique required to open the package without contaminating or damaging the device, and that the contents can be presented aseptically [1].

A recent poll collected at a Healthpack conference reported that, while only 13% of respondents don't incorporate user feedback, 47% perform usability testing and 30% "sometimes" do it [3]. Interestingly, 46% admitted that they don't know what sort of usability testing their company performs [3]. Without a solid foundation related to usability testing, it is unlikely that packaging engineers are prepared to meaningfully engage the new requirements. Among the reasons that this is happening is the limited guidance on where usability should be captured in the product development process. The FDA has issued a guidance document for assessing risks in use [4], which suggests that the design history file capture this information as a risk assessment activity [4]. Indeed, 21 CFR 820.30 (g), which pertains to design validation, provides the regulatory basis for this recommendation [5]. The FDA guidance document has suggested that these risks be vetted out with contextual inquiries, cognitive walkthroughs, simulated use testing, and observation [6]. Additionally, other data collection methods for task identification, such as interviews, are discussed in the document. These techniques, which rely on direct feedback from the end user, are meant to identify "critical" or safety-related tasks in a formative fashion, collecting information that can be used for future, contextually based usability inquiries. This behavior-level risk assessment is echoed in the IEC 62366 document referenced in ISO 11607, though neither standard is prescriptive in how this assessment is done, leaving the precise execution to those conducting the evaluations.

Currently, packaging professionals conducting design verification and validation activities typically employ experimental strategies, sometimes in contrast with the anthropological methods suggested in the FDA guidance document [6]. Companies with formalized human factors programs invest in teams locally who can conduct more anthropological methods in user work, or otherwise hire consultants to lead execution of these activities. Generally, however, packaging engineers lack the experience, training, or resources to conduct these types of studies in support of formative (early stage development) work throughout a project's life. Formative work may include a variety of strategies, one of which is focused on in the present work: the interview.

Medical device packaging is unique in that user interactions with packaging are specifically called out in clinicians' standards of practice. Two organizations which represent clinicians, and who issue recommended practices, are the Association of peri-Operative Registered Nurses (AORN) and the Association of Surgical Technologists (AST). For instance, AST's SOP III in AST Standards of Practice for Creating the Sterile Field, relates to small, sterile products includes guidelines specific to packaged products. The document specifically indicates:

> "Small wrapped items, peel packs and suture packets should be opened and "flipped" onto the sterile field using aseptic technique. The glued area of peel packs and suture packets is considered the boundary between non-sterile and sterile. Items should be opened in such manner that the nonsterile person is not extending over the sterile field." [7]

These represent guidelines; they are not standardized across organizations and not necessarily based on objective evidence, but instead tend to document accepted practice. They are written to be general, and to apply across a multitude of sterile packaging systems. Some direction, such as "not extending nonsterile surfaces over the sterile field and monitoring the field for potential breaches of sterility," are shared by both AST and AORN. However, recommendations are not universal (nor, when chased to seminal sources, are they evidence-based). For example, instructions regarding presentation of aa device to another team member ("picked" from the package), is expected by AORN (presentation by oneself to the field through a "dump" or "flip" is disallowed) but permitted by AST (i.e. it is anticipated that surgical technologists will dump or flip items onto the field). Similarities and differences between AST [7] and AORN [8], as they pertain to sterile package opening, are presented in Table 1:

Table 1: Comparison of AORN and AST on presenting to the sterile field

Topic	AORN	AST
Presenting	" Sterile items should be presented directly to the scrubbed team member or placed securely on the sterile field… Items tossed onto a sterile field may roll off the edge, create a hole in the sterile drape, or cause other items to be displaced, leading to contamination of the sterile field."[1]	"Small wrapped items, peel packs and suture packets should be opened and 'flipped' onto the sterile field using aseptic technique."[2]
Leaning over the sterile field	"Items should be delivered to the sterile field in a manner that prevents unsterile objects or unscrubbed team members from leaning or reaching over the sterile field. "[3]	"Items should be opened in such manner that the nonsterile person is not extending over the sterile field."[2]
Sterile region within the pack	"Peel pouches should be presented to the scrubbed team member or opened onto the sterile field by pulling back the flaps without touching the inside of the package or allowing the contents to slide over the unsterile edges of the package." [4]	" The glued area of peel packs and suture packets is considered the boundary between nonsterile and sterile."[3]

1 – AORN Standards and Recommended Practices, Recommendation VI-c
2 – AST SOP for Creating the Sterile Field, III-3c
3 – AORN Standards and Recommended Practices, Recommendation VI-b
4 – AORN Standards and Recommended Practices, Recommendation VI-e

The influence of packaging on aseptic technique is largely understudied. Limited work, primarily conducted in laboratory settings, has evaluated how contact with non-sterile surfaces is impacted by: package size [9], design and training [10], handling [11], opening in the proximity of a sterile field [12], and transfer of contaminates from outer to inner packs [13]. While these limited studies have employed quantitative, objective methods in laboratory settings to assess how design facilitates, or inhibits, aseptic presentation, the literature is devoid of explorative data which contextualizes how a package design influences or interfaces with an individual's approach to aseptic technique. In other words, while lab-based data is useful in quantifying design changes, there is relatively little published information available which can inform why designs are used a certain way. Also, while quantitative methods have obvious usefulness to packaging engineers, few tools have been demonstrated to gather critical baseline data regarding what is needed from the package design.

Understanding how a design might be interpreted and used by clinicians is no small challenge. A common practice intended to design packages that are useful to clinicians is to utilize AORN and AST guidance documents as a basis for creating heuristics in design (i.e., assumed uses; assumed needs). The aforementioned discrepancies and lack of objective information regarding the optimal approach to aseptic presentation makes the generation of optimized packaging design challenging. Will the product be presented to another for "picking", or flipped to the field by a single user? Does the packaging facilitate dispensing without being over the sterile field? What functionality do clinicians desire? What might the design communicate to the end user?

ASEPTIC PRESENTATION AS A PROFESSIONAL SKILL

Generally speaking, Packaging Engineers have very limited references regarding the needs and practices of clinicians. This is a gap, particularly in light of the finding that standards related to aseptic presentation are largely based in common, historical practices of practitioners that (for the most part) can't be traced to objective evidence. Indeed, AORN's own guidelines directly disclose scientific evidence is not available to support presentation guidelines [8]. Similarly, published literature is lacking in how aseptic presentation is implemented or how the guidelines may be interpreted by the end user. Designers are therefore tasked with generating baseline data about practical application of aseptic presentation independently, and there are few tools available to a packaging engineer for achieving this.

Research regarding workplace learning presented by Eraut [14],[15] proposes that numerous inputs contribute to how one performs job tasks; assumption of a "standard" set of experiences tends to ignore the learning history unique to the individual. Eraut [14] presents the learning process as dynamic- specifically, "flourishing" or "regressing" depending on how "group members" learn from each other. Similar phenomena emerge from the literature focused on situated learning literature; specifically, that group dynamics and relationships may influence access to certain types of knowledge [16] and, as such, behavior. These relationships in the workplace challenge any "one-size-fits-all" (i.e. standard) proposal of what procedures (e.g. practice that results in successful aseptic presentation) entail. In light of this, the challenge is not simply the lack harmonization between standards or practices described previously, it is that one concept (i.e., "flipping" into sterile fields) may have different interpretations depending on the perspective, experience and training of the end user.

The relationship between different design features and their ability to facilitate success with aseptic presentation is not widely understood. Much of the work in packaging usability research leverages psychology-based theories, such as affordance theory [17, 18]. The construct of affordances, as de la Fuente et al [18] discovered, have practical applications for packaging. Affordance theory provides designers a frame to build design cues into packages which influence the user to intended affordance actions and desirable outcomes (e.g. opening and transferring the item sterilely). While observational methods have repeatedly demonstrated their effectiveness in human factors work, there is little published work on other methods of identifying these affordances, particularly as it pertains to the use of medical packaging which carries the complex set of unstandardized rules previously discussed.

The first task in building the understanding of sterile packaging-focused affordances is understanding what information is perceived by the user. In Don Norman's book, *The Design of Everyday Things* [19],

Norman gives several examples of affordances with familiar objects, and how *signifiers*, also known as design cues, direct users to action based upon the affordances the object conveys. Norman described the signifier as a "perceivable indicator that communicates appropriate behavior to a person." Norman noted that signifiers are not always intentionally placed or present, and may communicate action without intention. de la Fuente's *Human-Package Interaction Model* (HPIM) [17] categorizes several stages at which communication can fail, from exposure (to a message) to action; it, combined with the affordance theory, provide a framework for organizing how a design behaves in the hands of a user. de la Fuente, Gustafson, Twomey, and Bix [18] demonstrated a practical application of using this model for affordance identification in a case study, successfully addressing a design issue with a pharmaceutical device's carton. Perceptible information can be captured in intrusive yet quantitative ways, such as eye-tracking, or in a cognitive walkthrough. In any case, what users perceive when they are interacting with medical device packages during aseptic presentation is largely unavailable in the published literature.

Although usability work in medical device packaging is conducted at the present, little is publicly available. A number of reasons likely contribute to the dearth of available information, including: constraints related to the safety and the need for privacy related to the contextual settings where these products are used; the difficulty in connecting behaviors to outcomes and the poor systems for reporting the same; and the competitive advantage that the information affords those who go to the trouble of carefully collecting it to name a few. Additionally, while there is clear guidance on what type of work needs to be conducted for design validation to meet 11607-1's requirements, very little work is available that 1) builds a baseline understanding from user experiences with medical packaging as it pertains to aseptic presentation 2) identifies what informs decisions regarding aseptic presentation. Specifically, information is needed which can be used to inform the summative/contextual methodologies directed by FDA's human factors in medical devices guidance document [6], and what types of learnings can be gleaned from these strategies. Work presented herein employs thematic analysis of interviews to gather insights regarding self-reported perceptions of healthcare providers related to aseptic presentation with focus on packaging.

The present work fills a gap in understanding by incorporating less-tangible inputs, such as personal understandings of the concept of "aseptic presentation" and context of the sterile theater; specifically, how factors in the environment affect the task of presenting a sterile device aseptically. These interviews gather salient experiences of the end users, including infrequent but memorable events. These contributions to the literature were supported by two principal objectives.

OBJECTIVES

The overarching objective of our work was to develop an understanding of how specific experiences of perioperative personnel and interpretations of "aseptic" affect aseptic presentation in sterile environments. In support of these, work presented herein focused on three proximal objectives. Namely:

- To develop a baseline understanding of design and non-design factors associated with the tasks that influence the method of transfer (i.e. a pick or dump)
    - Specifically, insights that could be used to inform summative assessments of package design with users in realistic contexts
- To garner insights into the decisions made by perioperative personnel related to aseptic technique

METHODOLOGY

RECRUITMENT

Participants were recruited via IRB-approved (IRB#13-383) flyers for the study. Flyers were sent via email using a subset of the AST listserv comprising AST members (with emails listed) that were located within a 30-mile radius from the site of the study (Michigan State University). Additionally, participants were recruited with emails distributed through a listserv for nursing students held by the College of Nursing (MSU). Inclusion criteria consisted of being 18 years of age, having no prior history of skin conditions (as a precaution for the observation package opening aspect of the study), and having prior experience as a healthcare provider. As a result of this recruiting practice, participants came from several hospitals, a local community college, and a university in commutable distance from the study location in mid-Michigan. Participants were recruited to partake in two parts of a single project: an opening study, which is out of scope of the present work, and the interviews presented herein. Thirty-nine (39) participants were recruited for this study, though 121 participants were recruited prior to interviews being added to the project.

Data were collected using a semi-structured interview methodology that followed a moderator guide crafted with study objectives in mind. All participants were audio- and video-recorded to fully capture comments and gestures. Recording equipment, a Sony digital camera and an Olympus audio recorder, were placed near or on the table where the interviewee and interviewer were seated. Semi structured interviews were transcribed verbatim post-hoc. The interviews ceased being transcribed when a "saturation" was reached. Saturation of data in context of the interview protocol comprised the point where no new insights were heard in the interviews related to study objectives.

MATERIALS

Six pouches, representing three different design concepts: large (Figure 1-1 and 2); long (Figure 1-3 and 4); and double barrier (Figure 1 5 and 6) were presented to participants to stimulate discussion and serve as a visual aid for gesticulation. The three, broad package archetypes were selected based on presentations and publications which provided evidence that their design characteristics presented challenges to healthcare providers [20, 21, 22, 23]. One of the archetypes chosen for the study (i.e., double barrier peel pouch; Figure 1, items 5 and 6) had consistently received positive feedback related to aseptic presentation in conference panels and surveys [20, 21, 22, 23] and, as such, was targeted for consideration. The other two archetypes were identified as problematic for asepsis by Cai [24]. Cai's work was comprised of a series of focus groups consisting of perioperative personnel and emergency medical services personnel and was focused on identifying problematic packages and features of the same. Incorporation of these three archetypes was decided based on the likelihood that memorable experiences (be they good or bad) would likely result in stories in which specific aspects of the design's usability would surface, thereby facilitating the identification of affordances and themes for analysis. Large packages (1 and 2), long packages (3 and 4), and double barrier packages (5 and 6) were prepared as visual cues to the participants. All packages included either a Tyvek top web substrate or a coated paper substrate sealed to a laminated film layer. Detailed information can be found in Table 2.

Fig. 1: Pouches used in the interview portion of the study. Pictured are large (1,2), long (3,4), and double barrier (5,6) pouches.

Table 2: Measurements, manufacturers, and materials of pouches.

Number	Pouch	Measurements (in x in)	Package manufacturer	Packaged product
1	Large	16" x 10+1/2"	Oliver-Tolas	Unfilled
2	Large	8+1/2" x 10+1/2"	DePuy Orthopedics	Unfilled
3	Long	1/2" x 18+1/8"	Teleflex	Intermittent Catheter
4	Long	2+5/16" x 21"	C.R. Bard	Foley Catheter
5	Double Barrier	10+1/2"x8+1/2"	Oliver-Tolas, Medtronic (inner)	Unfilled
6	Double Barrier	3" x 8"	Oliver-Tolas, BD (inner)	Syringe

INTERVIEW AND CODING METHODS

The moderator guide explored four topics including: experience with the identified packaged product types, aseptic technique, schooling/training, and the workplace. The guide itself was divided into 4 sections: large packages, long, packages, double barrier packages, and aseptic technique. Sections related to packaging probed for specific experiences with these package types, as well as inquired about how the clinician might present a device contained in one of these packages to the sterile field. Perceptions of "good" and "bad" technique with these sterile package types were probed to gather insights regarding an individual's interpretation of aseptic technique. To mitigate the effects of run order from fatigue during the interview, the packaging archetypes (long, large, and double barrier) were randomized in order of appearance within the participant interviews. However, aseptic technique was, by necessity, always the final section, since the authors did not want to prime the participant with by-the-book thinking before they discussed aseptic technique and packaging. The final section, Aseptic Technique, focused on inquiries related to work history, personal understanding of aseptic technique, and how the clinician came to that understanding. Questions also probed differences and similarities related to the concepts and techniques of sterile presentation between facilities, or between school and work, with discussion of aseptic technique centered on packaging and presentation of devices (utilizing packaging) to the sterile field. Packaging questions not only probed for opinions, but also the relationship of the design to function, specifically focusing on aseptic technique. Questions were purposefully vague and only more specific when probing questions were utilized for clarity.

The interviewer intentionally projected naïveté regarding the subject matter throughout the interview. This strategy, which puts the interviewee in the role of a "teacher" and the interviewer in the role of a "learner", is recommended by Glesne in order to mitigate the risk of biasing the participant from providing answers they think the interviewer wishes to hear [25]. A single researcher, the interviewer, transcribed videos and audio recordings of the interview verbatim manually. Audio was reviewed at the recorded speed, and inaudible words

were transcribed as "inaudible". In the transcripts, personal names and places of employment were redacted and, in some cases, replaced with general labels (e.g. participant number in place of name, etc.).

RESEARCH CODING

Two researchers coded and analyzed transcriptions. The primary coder had conceptually studied aseptic technique (in standards and practice) for several years. Additionally, he had industry experience and exposure to medical device packages. He had previously consulted on human factors projects and was primarily responsible for both the methodological strategy and literature synthesis. His role in the present study was to participate in the first pass of coding, to ideate with the second coder in the generation of the final code book, and to re-code all of the transcripts for the final analysis.

The second coder, while familiar with medical device packaging, did not share overlapping research or industry background. She similarly researches human-package interaction, but with a focus on packaging waste streams. The secondary coder was invited into the project by the primary coder for this project and given a cursory explanation of the research objectives and theoretical lenses. She was encouraged to code the data in the first pass using her own interpretation of what was said. After both coders discussed their coding, the primary coder re-formulated the codebook and re-coded the transcripts.

CODING STRATEGY

Data were analyzed using a thematic analysis [26]. QDA Miner software (Provalis Research; Montreal, QC) was used to in the construction of the thematic analysis. Themes were constructed using summative codes and categorized into several over-arching topics, from single-cases to topics that spread across multiple interviewees. Each coder conducted a preliminary reading of all participants' transcripts to formulate tentative structures of a first pass codebook before coding. Coders worked independently in the first pass of coding, only discussing themes after all transcript coding had been completed. Different interpretations were reconciled through consensus discussion to develop the final codebook.

To report the prevalence of codes across interviewees, a structure was developed by the primary coder. Codes that were present in >60% of the participant interviews were categorized as "Major Themes". Similarly, codes that were in 40-60% of the participant interviews were classified as "minor themes". The categorization of "major" and "minor" did not determine the *importance* of a code or theme, but simply served to provide a starting position for the analysis. To be clear, any given code's quantitative prevalence was not necessarily an indicator of comparative value versus other codes.

Prevalence was calculated using QDA Miner's "Retrieve Segments" command, which locates codes throughout groups of transcripts and reports descriptive statistics on the prevalence and quantities. Codes are reported herein using percentages to denote this prevalence across participant transcripts (proportion of participants indicating a given theme). Broad themes were further assessed in an attempt to identify how external influences, design factors (both product and package) and user characteristics impacted the decisions made. Discussion of the codes will utilize the participant's own voice (i.e., words) to provide examples of the themes named by the research team.

RESULTS

PARTICIPANTS

A total of 39 participants were recruited and interviewed after meeting screening criteria. One participant's data was removed post-hoc as a review of data sheets after the study revealed that they did not report the experience required by screening criteria (namely experience working as a healthcare provider), leaving 38 participant interviews. Participant interviews were transcribed beginning with Subject 122 who was the first participant recruited for interview. Saturation was achieved after 15 participants. Transcriptions of these interviews ceased when no new insights were gathered regarding work in a sterile environment, or opening packages aseptically. This coincided with participants from the nursing student listserv due to these participants lacking experience with the topic of interest. Although all of the participants were interviewed and given incentives, the interviews were not transcribed (and, therefore, were not present in the analysis).

The average age of the 15 participants with transcriptions was 38.7 (Std.Dev ± 9.4 years); a participant did not provide an age. Participants were fairly experienced; on average, they had 9.8 years of experience in healthcare (Std.Dev ± 9.5 years) and averaged 8.13 years of experience aseptically presenting items to sterile fields (Std.Dev ± 7.78 years). Interviewees were predominately female (14/15) surgical technologists (13/15). One male surgical technologist and two female nurses participated in the study. Table 3 provides the age, experience, gender, and profession of each of the transcribed interviewees.

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Table 3: Interviewee ages, experience, gender, and profession

Subject	Age	YE-Healthcare (years)	YE-Aseptic (years)	Gender	Profession
122	37	8	8	Female	Surgical Tech
123	41	13	13	Female	Surgical Tech
124	38	16	16	Female	Surgical Tech
125	51	30	3.5	Female	Nurse
126	23	0.5	0.5	Female	Surgical Tech
127	34	12	12	Female	Surgical Tech
128	Not Reported	1	1	Female	Surgical Tech
129	55	1	1	Female	Surgical Tech
130	38	9	9	Female	Surgical Tech
131	46	28	28	Male	Surgical Tech
132	51	2.5	3	Female	Surgical Tech
133	35	14	14	Female	Surgical Tech
134	24	1	1	Female	Surgical Tech
135	36	1	1	Female	Surgical Tech
136	34	11	11	Female	Nurse

A labeling scheme was developed to provide an alphanumeric label for each participant; participants were labeled by their profession (e.g.,ST or N), followed by their participant number (e.g., ST133), followed by their years of experience aseptically presenting items to the field (e.g., ST133-14). Participants were numbered in accordance with their sequence in the total project.

The codes assigned to the transcribed text were fitted to larger schema as needed. Table 4 provides some examples of how codes were assigned using the "material curling", which indicated that the material affected the ease of dispensing the product:

Table 4: Coding Process Example for Thematic Analysis

	Participant Voice	Phrase of Interest	First Coding Pass	Final Code
126	I guess similar to the other one. I'd break off the corner points and then I would start from the middle point and try to control the corners.	"control the corners"	"Try to control material"	Material curling
127	I would, if it's a sterile peel pack like this, I'd start at the middle and then like go [walking grips to far corner], say north or south on the package, and continue down the seams. So I could try to have a bit more control over the edges and keeping them away from the contents of the package.	"more control over the edges and keeping them away"	"Try to control material"	
128	Watch your corners… your corners is what gets you. On everything, no matter what kind of package it is.	"watch your corners...your corners is what gets you"	"Monitor material"	

RESULTS

Codes were tabulated by the software and organized by topic (See Table 5). In instances where positive and negative opinions were given on certain topics (e.g., size/shape of the device), plusses (+) and minuses (-) were added to clarify directionality of the opinion.

Table 5: Table of Major themes and sample quotations qualitative analysis

Organization of Themes by Topic
Packaging
Ease of Dispensing - Material curling (-) (60%)
"it's harder when I start at the point [chevron] and it's connected at the corner, if I peel it back and sometimes [the corner] snaps off and goes back and touches [the device]" - ST126-0.5
Ease of Dispensing - Size/shape of package (-) (60%)
"We also have one that's like a 3 foot-long and that is not easy to open at all. You're like, over your sterile field and you're supposed to be away from your sterile field, not over" – ST128-1
Ease of Dispensing - Double barrier (+) (60%)
"I really like the double barrier, because then if the first barrier is somehow contaminated, or compromised, then you still can–you don't have the waste the product because you can try to open it again because it is inside another sterile pouch." = ST123-13
Aseptic Technique
"Over the field" (80%)
"... if you're really good at it, you could peel it back, [flip over field] and present it like that, so this is covering–the part of the package is covering your arm that you're presenting to the field. Because there's no way really that you can open these longer packages without actually being over the field" – ST132-3 *"Flipping...I'm wondering if that's even a good practice. Because we generally don't open stuff over our sterile field. Because the outside of that item would not be sterile" – N125-3.5*
Dispensing method - Picking: Size and shape of the device (60%)
"If it's the real long ones, to try and do it yourself is–you're going to contaminate it. You will. It happens. Depends on the size, the longer it is–you should really be picking it out of the package from someone." -ST130-9 *"If they get too large and something is too bulky ... we'll just open them to another team member, what you call picking," – STT135-1*
Dispensing by one's self - Staff Availability (60%)
"Any situations where single staff, um...well when you're opening a case and you're the only person in the room. That's the dumping and the tossing, no picking" N125-3.5 *"I would say it definitely depends on staff availability and the amount of help we have to get the case ready... if there's just a nurse and a tech in the room, then that tech is mainly responsible for opening the room because the nurse is doing things at the computer, or finishing up charting... So you just have one person opening everything" ST127-12*

Several themes attained the "major" level of prevalence in the interviews (defined as having more than 60% prevalence in the interviews). These included: a negative perception of package sizes and shapes (60%), negative experiences related to material curling (60%), a lack of staff availability influencing the need to dispense by one's self (60%), as well as the size and shape of the device influencing whether an item is picked or dumped (60% i.e., larger items requiring assistance for removal), and discussion of going "over the field" the plane of the sterile field (80%). The latter topic of "over the field" concerned behaviors in the operating room with respect to dispensing devices into sterile fields aseptically from their packaging. Consistent with previous findings from Benolken [20, 21, 22, 23], a major theme that emerged from our participants was that double barrier packages (60%) were well received.

Minor themes in the interviews included more communal aspects related to working and learning, such as: watching others (46.7%) being critical of other's technique (46.7%), being instructed on how to specifically open packages from experienced colleagues (40%), and (broadly) learning aseptic transfer from experienced colleagues (46.7%). Topics such as the influence of item rigidity on how products were dispensed (46.7%) and biomechanical limitations (i.e., length of arms and height) affecting the ability to use the package (40%) were among the minor themes. An additional topic that surfaced in a third of the interviews was packaging fiber tear (33%); this topic is noted here due to its role as an "automatic" contamination risk per nursing/surgical technology SOPs.

Generally speaking, participants did not report stark differences between hospitals with respect to aseptic technique. Where participants learned aseptic technique was consistent across interviews; participants learned the skill in school (100%), while working in their hospital clinicals (73.3%), and by gaining personal work experience (60%). The differences reported by participants were largely procedural in nature (e.g., prep times varying by type of surgery, and the amount of package opening pre-surgery varying by hospital) (53.3%). However, influences due to the availability of staff and product morphology revealed interesting insights to the possible differences that exist in individual approaches to aseptic presentation. Additionally, there were notable interactions with colleagues (i.e., scaling down "book learning") and interpretations of sterile surfaces (i.e., interior of packaging) that surfaced in the data. These are highlighted and discussed in the following sections.

PICKING VERSUS SINGLE STAFF MEMBER PRESENTATIONS (FLIPPING)

STAFF AVAILABILITY

The issue of available staff having influence on the approach taken to open sterile packaging was discussed in a majority (60%) of the conversations. Simply, presenting an item to someone else was not feasible as "there are times on the weekends when you're the only one getting the room [ready], because… the staff is lighter". Additionally, emergent situations were reported to result in situations in which "you have one person…in a separate basin away from the main sterile field, they'll just be dumping stuff into that just to get it ready really quick for you".

PRODUCT INFLUENCES

The design of the product itself often factored into decisions to pick or dispense the item oneself (60%). Responses in this vein varied, but included the desire to pick "something long and cumbersome", something "past a certain size… or weight", or because of "the awkward shape of what's in there". Devices that were quite flexible were reported (46.7% n=7/15

participants) as challenging aseptic presentation, particularly when the device and the packaging material were "flopping around on you", in the case of long items. Although infrequently mentioned, the cost of the product potentially influences the willingness to present the item alone because, as one participant put it, "you're always worried that you're going to drop [expensive devices] on the floor… and those we would open with the picking".

WORKPLACE LEARNING AND ASEPTIC TECHNIQUE

SCALING DOWN

Not surprisingly, mentorship at work was often indicated (46.7%; n =7/15 participants) as one way that participants learned aseptic technique. An interesting element of this was the "scaling down" discussed by one of the participants, particularly as it pertained to single staff member presentations. This "scaling down" referred to the tendency for the mentor to moderate some of the training received at school. The distance from which a clinician could be from the sterile field when aseptically presenting packaged devices was jokingly described as "you don't need to be 500 yards away throwing these [items]. While not reported by enough of the interviewees to become a theme, it does give an example of how practical work practices may not always coincide with what is being taught in formal education.

EXPERIENCE SHARING

Participants reported gaining understanding relating to packaging and aseptic technique while on the job with colleague through sharing of experiences (46.7%; n=7/15 participants). For example, participants mentioned that they were told to "hold this until somebody's scrubbed in" or that a particular package was "hard to open" and to "…set it here [on the table] and open the top and we'll grab it out". These situations were some of the few examples of non-training related learning about aseptic technique and how new designs were engaged.

NOTED AFFORDANCES RELATED TO PACKAGING

POSITIVE AFFORDANCE – SHIELD-ABILITY

Most participants (80%; n=12/15 participants) discussed the possibility of non-sterile surfaces (e.g. the arms of a "circulating" or non-sterile clinician)) being over the sterile field during presentation. Given that both the AORN and AST standards caution against this, and that limited work [12] has demonstrated that forces related to opening packs may spread microbes to a sterile field, this is a particularly interesting finding. In addition to its obvious relevance to sterile practice, this topic shed light on the possibility that utility of the package may be perceived differently depending on the end user. Some users (26.7%%; n=4/15), suggested that packaging provides users with the opportunity to serve as a "shield" between them and the sterile field; that is, that it provided a barrier, enabling them to break the plane referenced in the standards [7,8]. An example of this use of packaging can be referenced in Figure 2.

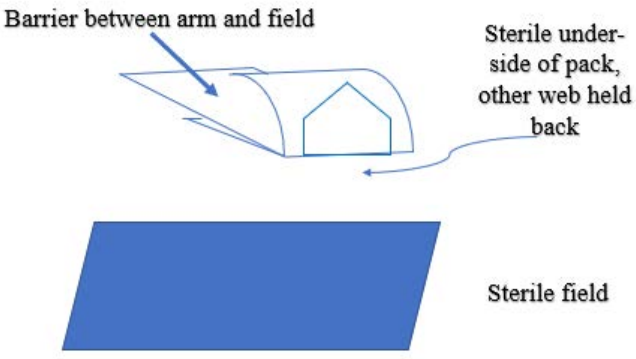

Fig. 2: Presentation over the sterile field

One participant explained the sentiment, indicating, "even if you are over, again you're creating a barrier with [the pouch material] because inside is sterile and outside is not, and you have the outside against your skin and the inside is facing [the field]." This type of thinking was challenged by another interviewee, since "you don't want [a] hand that's unsterile [over the field]". In both of these specific cases, the participants identified parts of their bodies as non-sterile, and recognized the necessity to keep non-sterile objects away from the field., , The affordance behaviors of some clinicians related to aseptic technique, particularly how they interact with the sterile barrier system, and how they interpret the standards related to what's appropriate for aseptic transfer, differed greatly in opening approach and how they viewed their ability to safely interact with the field during transfer of sterile devices.

NEGATIVE AFFORDANCE – CONTAMINATION

A majority of participants (60%; n=9/15 participants) identified a specific issue with the packaging film material: its tendency to curl. Exposure of the outer portion of the packaging to distribution and healthcare environments create a scenario where the outside of the package is not sterile, while, (if the barrier performs its job) the inside is. This reality creates a situation where an inward curling of material means non-sterile portions of the pack are moving into the vicinity of the device and non-sterile surfaces potentially transfer components to sterile areas (including the device), or to the person making the transfer who is fighting to minimize the curling of the material. Conversations regarding material curling centered around preventing contamination and difficulty that results in successfully presenting aseptically presenting devices to a sterile field. One participant, using a large chevron pouch (Tyvek sealed to a polyester laminate), pointed out that the film was "folding in" and that she had to be "very careful with that when the object comes out, that those sides are not going to touch what's coming out". An example of the polyster portion of the pouch curling inward can be seen in Figure 3.

Fig. 3: Curling pouch material

DISCUSSION

Researchers and packaging professionals have much to gain by better understanding user's historical experiences related to the performance of sterile barrier systems and the task of aseptic presentation. Further, insights regarding the rationales providers utilize when determining actions related presentation of devices have the potential to inform summative usability studies intended to enhance design utility. For instance, contextual limitations, such as staff availability, may affect the approach to the task at hand, and as such, varied staffing levels are a factor to consider in formal usability trials which incorporate contextual factors. Based on our study,

affordance behaviors regarding opening are undoubtedly impacted by this context. Beyond that, they are also individually moderated by one's understanding of aseptic technique. This study employed thematic analysis in interviews to gather insights about self-reported influences of salience to the end user.

The study had two primary objectives: to build an understanding of design and non-design factors that influenced the method of dispensing packages via aseptic presentation, and to garner insights related to the clinicians' perceptions of what constituted aseptic technique. For the former objective, we were successful identifying one consistent contributor to this decision. Staff availability was identified as a contributor to the decision to present by one's self. Some specific comments, which weren't themselves frequent enough to form over-all themes on their own, identified device length/floppiness, product cost, and size/weight as contributors to the decision to present to a scrubbed colleague. However, much was learned with respect to the interactions with colleagues. Examples from the interviewees included sharing experiences with colleagues, as well as "scaling down" new trainees. These types of interactions should be of interest to designers and challenge using "standard" understandings of how one might come to the decision to "pick" or "flip". The second objective, to garner insights into the perception of aseptic technique, successfully challenged the use of a template for the skill. Participants, in some cases, applied aseptic principles differently based on their interpretation of what was being "over the field" (i.e., non-sterile arms over the field shielded by the packaging). This finding may be of interest to designers who may see clinicians use their package designs in similar ways.

Design engineers have the impossible task of quantifying and *standardizing* risks, particularly as they pertain to use error, and how design inputs can quantifiably mitigate these risks. As the present work has demonstrated, boiling down a user group ("nurses" or "surgical techs") into a boilerplate template may not be realistic. ISO 11607-1, as of 2019, is guiding the industry to become more involved with the end user, particularly as a design validation activity to confirm the final design's conformance to aseptic principles.

The new regulatory environment, in alignment with ISO 11607, has formalized the need for usability evaluation related to packaging, representing an important first step in this new frontier and establishing the important role that packaging can play in patient outcomes. The expectations for user-pack evaluation are, simply stated, that one validates the design with simulated or actual use. However, in the development process, formative work is also important, yet little guidance is available to packaging engineers with respect to data collection. The work herein presents affordance theory and workplace learning in a practical, packaging context and demonstrates the utility of one of the tools (interviews) found within the FDA guidance document. This work provides a framework and a demonstration of how some of these learnings can be gleaned. Importantly, it also demonstrates a method for organizing and interpreting the body of findings one is collecting during formative work. The present work, using these tools, generated baseline data regarding some of the perceptions of what constitutes "aseptic presentation", as well as generated foundational data on the reasoning behind employing "picking" and "flipping" or "dumping" methodologies. These understandings of the clinicians' reasoning and experiences may indeed serve to inform simulated usability tests and what type of "stress testing" to employ on packaging designs with respect to the environment created for research participants. For instance, an engineer may wish to evaluate controlled situations with two participants (picking), and a more expedited test where the participant is

alone (flipping). In short, these baseline data may inform what type of experiments one should conduct. Some questions, without this formative groundwork, may not be asked by the experimenter and key insights may be missed during the actual usability evaluation.

The present work focused on the interview, but specifically how to apply thematic methods to learn more about the user's experience. The gap in strategy guidance is therefore partially addressed by the present study. The work has demonstrated that discussions with customers, if not solely focused on customer preference, can reveal unique insights that may have been previously hidden from the designer. Although the present manuscript used existing theory to help inform the structure of the interview, which indeed facilitated the types of learnings reported herein, packaging engineers can (even without academic frameworks) use coding strategies to theme and organize their data. This is particularly useful in stages of the projects when designs are still conceptual and the needs are not yet known.

LIMITATIONS

Although the present work has demonstrated a method and framework for packaging engineers to learn more about the user experience, there are notable constraints due to the method. This work has demonstrated a method of gathering contextual learnings using largely *self-reported* experiences. While the method is enticing due to resource constraints during highly iterative project work, it is important to note that it's possible that one may articulate a behavior that one does not actually employ in practice. Additionally, there are behaviors one may not be able to articulate! These potential discrepancies related to accuracy of reporting are an innate shortcoming of the method; as such, they are intended to be formative in nature. Observational confirmation should be used in additional studies in order to reach the summative/validation stage of the packaging design. Packaging professionals should not treat interview work as a short-cut to expedite validation and draw early conclusions related to usability. Although we have successfully applied thematic analysis to identify self-reported affordances and potential contextual influencers with respect to aseptic presentation, we caution readers that although a thematic analysis can allow one to identify design inputs of interest, it is generally the expectation of the FDA that any risks are thoroughly vetted in a simulated- or actual-use study. Specifically, if one wishes to claim compliance to the new iteration of ISO 11607-1 (2019), interviews, focus groups, and marketing activities will not meet the new requirements. The thematic method is useful and can potentially be illuminating, but the importance of end-user simulation or rea l use studies (which is notably required under the new 11607-1 requirements) cannot be understated. Additionally, the specific scenarios that the thematic method may facilitate good data collection are not known. For instance, confirming the effectivity of a design change may not be well served by such an interview. Simulated or actual use may be a more effective method, as demonstrated by de la Fuente et. Al [18].

Further, because these are personal accounts, they are not intended to be generalized to every individual nurse or surgical technologist (or context). In fact, the message of this work is that easy and generalized heuristics in design do not necessarily capture all of the pertinent details to a package's actual use. It is important to note that this investigation was qualitative in nature, and the experiences of participants were used to contextualize existing theory within medical packaging by investigators intimately familiar with these topics. The same data may be interpreted differently by those with different academic backgrounds, or with a different sampling nurse and surgical tech demographics. The sampling in the present work was predominately female.

Another limitation with this work is that it is often difficult to know how the affordances were first perceived. Did a colleague call attention to the affordance of "shield-ability" (as this manuscript has named) when presenting over the field? Did the participant independently notice it? The answer to this question would be useful to understand how affordances are disseminated in the workplace but the design of this study was not allowed to go to that level of analysis.

Another limitation of our student is an overrepresentation of women. Data from the statistics of the labor bureau indicate that approximately 88.3% the nursing, psychiatric workers and home health aides are comprised of females, and indicates that 73.8% of "clinical/laboratory technicians" are female. In our sample 93% were female, and 7% male. Our sample (obviously) over represents females. That said, labor statistics indicate that a large proportion of the population that we are working to represent is female.

A final caveat to the present study is that the necessity of the recommendations set forth has yet to be established. Simply put, there are few studies which deal with topics such as presenting items over the field. Beyond complying with CDER and CDRH's human factors guidance document, a real-world connection to health outcomes has yet to be established. In either case, better supporting nurses and surgical technologists and ensuring that design does not inhibit their important work activities must be a priority for the industry.

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